JAN 2 2 2002 **Attachment #2**

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K012602

1. **Submitter's Identification:**

Crosstex International, Inc.
10 Ranick Road
Hauppauge, New York 11788
Tel No.: 631-582-6777
Fax No.: 631-582-1726

Contact Person:

Mr. Richard Allen, Sr.
President
Crosstex International, Inc.
10 Ranick Road
Hauppauge, New York 11788
Tel No.: 631-582-6777
Fax No.: 631-582-1726

Date Summary Prepared: July 27, 2001

2. **Name of the Device:**

- Crosstex® Isolite® Earloop Face Masks – Blue, Pink
- Crosstex® Isofluid® Earloop Face Masks – Blue, Pink, White, Green
- Crosstex® Isofluid FogFree® Earloop Face Masks – Blue, Peach
- Crosstex® Isofluid FogFree® Face Masks with Splash Visor – Blue, Peach
- Crosstex® Procedural Earloop Face Masks – Blue, Pink, Yellow
- Crosstex® Ultra Fluid Resistant No-Fog® Earloop Face Masks – Blue
- Crosstex® Ultra Fluid Resistant No-Fog® Face Masks with Splash Visor - Blue

3. **Predicate Device Information:**

a. American Threshold Industries, Surgical Masks, K# 801036, Asheville, North Carolina

b. American Threshold Industries, Fluid Resistant Masks, K# 955556, Enka, North Carolina

4. Device Description:

The seven (7) Crosstex® Surgical Masks are constructed of either an inner/outer facing of medical grade tissue or 100% spunbonded polypropylene, a 100% meltblown polypropylene filter media, with white elastic loops and/or a fogfree strip. The nose piece for all seven (7) Crosstex® Surgical Masks is 27 gauge aluminum wire, some have an anti-fog strip, with the Crosstex® Ultra Fluid Resistant No Fog® having a vapor barrier. All of the materials used in the construction of the Crosstex® Surgical Masks are being used in currently marketed devices (see predicate information).

5. Intended Use:

The following Crosstex® Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids.

- Crosstex® Isolite® Earloop Face Masks – Blue, Pink
- Crosstex® Isofluid® Earloop Face Masks – Blue, Pink, White, Green
- Crosstex® Isofluid FogFree® Earloop Face Masks – Blue, Peach
- Crosstex® Isofluid FogFree® Face Masks with Splash Visor – Blue, Peach
- Crosstex® Procedural Earloop Face Masks – Blue, Pink, Yellow
- Crosstex® Ultra Fluid Resistant No-Fog® Earloop Face Masks – Blue
- Crosstex® Ultra Fluid Resistant No-Fog® Face Masks with Splash Visor - Blue

6. Comparison to Predicate Devices:

See Attached

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

a. Fluid Resistance:
   - Liquid (Water) Resistance Test/Impact Penetration Test
b. Bacterial Filtration Efficiency (BFE) / Differential Pressure (ΔP) Tests
c. Flammability Testing
d. Latex Particle Challenge Test
e. Biocompatibility Testing Per ISO 10993

It was our conclusion that Performance Testing met all relevant requirements of the aforementioned test standards.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The Crosstex® Surgical Masks have the same intended use and technological characteristics as the predicate devices. Moreover, bench testing contained in this submission supplied demonstrates that the technological characteristics do not raise any new questions of safety or effectiveness. The Crosstex® Surgical Masks are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

Crosstex, International
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K012602
Trade/Device Name: Crosstex® Surgical Masks
Regulation Number: 878.4040
Regulation Name: Surgical Mask
Regulatory Class: II
Product Code: FXX
Dated: November 20, 2001
Received: November 26, 2001

Dear Ms. Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012602

Device Name: Crosstex® Surgical Masks

Indications For Use:

The following Crosstex® Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids.

- Crosstex® Isolite® Earloop Face Masks – Blue, Pink
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012602

Prescription Use ____ (Per 21 CFR 801.109) OR **Over-The-Counter Use** ____ (Optional Format 1-2-96)